ORIGINAL ARTICLE

# The Safety and Satisfaction of an Innovative Eye Shield Detecting Head Position for Post-Operative Intraocular Surgery

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**Objective**: To propose an innovative head-tracking device integrated into a standard postoperative eye shield to improve the care of gas-filled eye patients. The present study aims to evaluate the satisfaction and compliance from the users of this device.

**Materials and Methods**: Five healthy volunteers were assigned to use the innovative eye shield for three days at their home and instructed to maintain facedown positioning at all times. Subjects graded their satisfaction and safety scores. Twenty-four hours of positioning data were obtained from the phone devices connected to the eye shield by Bluetooth® system. During the study, an application in the phone will alarm if the participant's head is in the wrong position (more than 15 degrees of the reference). Participants were interviewed about their satisfaction concerning the issue on the third day of the study.

**Results**: Of the five subjects, four were males, and one was female. The mean age was 51.8 years old. From the questionnaires, the majority of subjects were satisfied with the appearance, weight, audio-vibrating level, wearing comfort, and easy instruction (median 5, 5, 5, 4, and 5, respectively, range from 1 to 5). For head positioning compliance, participants maintained their head positioning better in the daytime versus nighttime. The third day had worse compliance compared to the first and second days. For the safety issue, none of the participants reported the blackout of the instrument, short circuit, or skin burn event. Mild irritation from the medical tape was reported from one subject.

**Conclusion**: The innovative eye shield is safe and improves patient compliance in maintaining head positioning after gas-filled intraocular surgery.

**Keywords**: Retinal detachment; Macular hole; Vitrectomy; Intraocular gas/oil; Post-operative head position; Tracking device

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Management of retinal detachment and full-thickness macular hole is usually related to the use of an intraocular gas/oil tamponade technique. Head-positioning after injection of gas/oil is an essential factor resulting in the success of the procedure. Both Guillaubey et al. (2008) and Lange et al. (2012) have reported that post-operative face-down positioning in macular hole larger than 400 microns has a greater success rate than non-face-down position[1,2]. In addition, the correct facedown head-positioning prevents complications from the gas/oil bubble, including cataract, corneal endothelial dystrophy, and acute angle closure glaucoma[3,4]. However, to maintain the correct head-positioning is difficult. Verma et al. (2002) and Leitritz et al. (2014) had shown that subjects can maintain the correct head-positioning less than half of the time over 24-hour period[5,6].

The authors' previous publication on the innovative eye-shield's reliability and in vitro safety demonstrated high reliability in monitoring the head position and provided the real-time audio-vibrating feedback using an android smartphone application[7].

The study aims to evaluate the safety and the satisfaction of this innovative eye shield. Furthermore,

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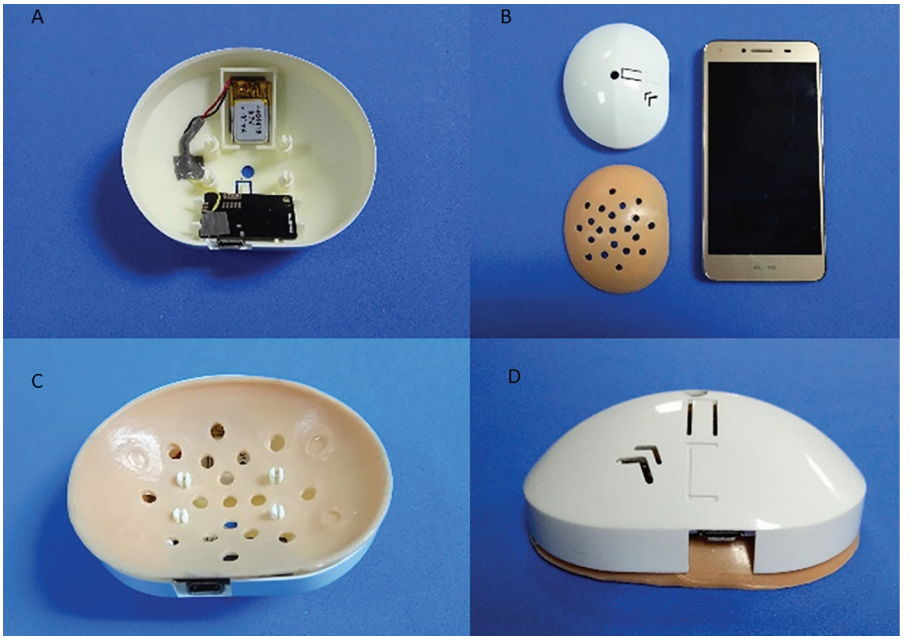


**Figure 1.** The innovative eye shield (white) and the ordinary eye shield (orange). (A) electronically system, (B) parts of the innovative eye-shield and connecting device, (C) Inner contact side of the eye shield, and (D) External appearance of the innovative eye-shield.

the volunteers' head positioning compliance are reported.

## Materials and Methods

### Subject and protocol

The present study was a prospective descriptive study in five healthy volunteers between January 2018 and March 2018. The study was approved by the Local Institutional Review Board (IRB CoA: 986/2017) of the Faculty of Medicine, Chulalongkorn University, Thailand, and followed to tenets of the Declaration of Helsinki. Consents were obtained from all subjects before participating in the experiment.

All subjects in the present study were Thai individuals volunteered to the study and met all the inclusion criteria, including 1) be a healthy person, aged more than 18 years old, 2) Have no health issue related to headache, migraine, vertigo, neck, or back pain, and 3) Have no previous neck or back surgery. The authors excluded subjects who were unwilling to undergo informed consent for study participation.

All subjects were informed about the nature of the diseases and the important post-operative head-positioning. Then, subjects were trained on how to use and reattach the devices by themselves by the investigator. They were instructed to wear the device and maintain the specific face-down position for 3-consecutive days as strictly as possible. Subjects were required to fill in the daily questionnaires. The questionnaires surveyed about the satisfaction in terms of device's appearance, comfort, safety, and any adverse event found while using the device. On the last day, after removal of the devices, subjects were interviewed for their activity disturbance and any other recommendation. All participants were trained to use the instrument and to apply the instrument before starting the study. 3M™ transpore medical tape was used to apply the instrument with the participant's skin. The investigators obtained the continuous head position recording data from the device's memory card on the last visit.

The main variable of the present study was the safety and satisfactory score graded by the subjects. The authors also observed adverse events while using the device. Moreover, the authors reported the head-positioning compliance of these volunteers.

### Devices

A low-power microcontroller (MCU) integrated with a Bluetooth low energy (BLE) module, a 3-axis accelerometer, and a power management sub-system were placed in the plastic model, designed to enclose the ordinary eye shield as shown in Figure 1. Its dimensions were 10×20×35 millimeters. The total weight, including a rechargeable battery, was 8 grams. This device was waterproof. It had a round edge, and smooth surface that can be secured in place on the normal medical eye-shield.

**Table 1.** Demographic data

| Subject No. | Sex | Age (year) | Education | Career | Underlying disease |
|---|---|---|---|---|---|
| 1 | Male | 57 | BD | Retiree | Hypertension, diabetes, dyslipidemia |
| 2 | Male | 64 | High vocational certificate | Retiree | Hyperuricemia |
| 3 | Male | 26 | BD | Graduate student | None |
| 4 | Female | 54 | BD | Teacher | Hypertension |
| 5 | Male | 58 | BD | Trader | Hypertension, diabetes, dyslipidemia |

BD=Bachelor's degree

**Table 2.** Duration of head positioning within 15 degrees from the reference point (percentage of the time)

| | Subject 1 | Subject 2 | Subject 3 | Subject 4 | Subject 5 | Mean | SD |
|---|---|---|---|---|---|---|---|
| Whole day | | | | | | | |
| Day 1 | 6.25 | 38.79 | 13.89 | 30.36 | 25.91 | 23.04 | 13.00 |
| Day 2 | 19.03 | 45.45 | 12.5 | 22.22 | 22.6 | 24.36 | 12.47 |
| Day 3 | 4.98 | 27.97 | 14.83 | 18.99 | 21.15 | 17.584 | 8.50 |
| Daytime | | | | | | | |
| Day 1 | 9.77 | 44.84 | 13.89 | 26.40 | 37.09 | 26.40 | 14.89 |
| Day 2 | 25.27 | 41.26 | 10.03 | 36.11 | 32.42 | 29.02 | 12.11 |
| Day 3 | 11.38 | 41.75 | 13.15 | 18.99 | 20.19 | 21.09 | 12.14 |
| Nighttime | | | | | | | |
| Day 1 | 4.42 | 13.89 | 2.61 | 9.28 | 5.17 | 7.07 | 4.53 |
| Day 2 | 0.97 | 20.24 | 9.09 | 6.19 | 2.78 | 7.85 | 7.60 |
| Day 3 | 1.74 | 18.68 | 7.83 | 0.00 | 3.51 | 6.35 | 7.48 |

SD=standard deviation

The acceleration data were transferred to the MCU 10 times per second in testing mode and once per five minutes in ambulatory mode. The device communicated with the custom Android application on a mobile phone via the BLE wireless system.

All devices were certified by the electrical and electronic products testing center (PTEC) - the electrical testing center for EMC, product safety, medical devices, energy testing, and electronic equipment with ISO/IEC 17025 certification.

### Statistical analysis

The authors collected the data from the mobile's memory card to a personal computer. The data were analyzed descriptively using percentage, median and interquartile range (IQR), minimum (min), maximum (max), mean, and standard deviation (SD). The analysis was performed using the Microsoft Excel® 2013 software.

## Results

### Demographic data

From five subjects, four were males and one was female. The mean age was 51.8 years old (ranged between 26 to 64 years old, SD 14.87). Other demographic data is shown in Table 1.

### Safety and a satisfactory score

From the questionnaires, the majority of subjects satisfied the appearance, weight, audio-vibrating level, wearing comfort, and easily instructed (median 5, 5, 5, 4, and 5; IQR 0, 0, 1, 1, and 0; min-max [5], [5], [4 to 5], [4 to 5], and [4 to 5], respectively). Most subjects responded that they relied on the device sensor (median 4; IQR 1; min-max [3 to 4]).

There were no serious adverse events reported from any subject. One (subject No. 2) reported mild irritation while using 3M™ transpore medical tape, but the symptom cleared after changing the type of the tape. None of participants reported on the blackout of instrument, short circuit, or skin burn.

### Head positioning compliance

The authors recorded the data every five minutes. The data showed that subject No. 2 has the best head-positioning compliance, within 15 degrees from the reference point. In the second day, half of them improved their compliance while the other half worsened their compliance. However, compliance declined on the last day. There was a declining trend

in daytime and nighttime. Subject No. 2 had the best compliance in both periods. Subject No. 3 did not do well during the daytime but improved at night by 7%. Furthermore, the authors found that all subjects can maintain their head position less than 20% of the time during the night.

## Discussion

There have been many innovations created to improve head positioning compliance in patients with gas/oil-filled eyes. For example, Boucher et al. designed prism spectacles that vertically convert the viewed object while patients were in face-down positioning[8]. Gao et al. created the assistive table and the stainless frame to comfort the patient's neck and shoulder[9]. Moreover, this stainless frame with a special pillow is still used today by post-operative patients at King Chulalongkorn Memorial Hospital.

In 2014, Leitritz et al. created an electronic sensor to detect actual head posturing compliance[6]. After that, Brodie et al. designed a headgear sensor that provided audiovisual feedback to monitor the head positioning[10]. They concluded that the audio feedback might improve compliance. Their study was similar to instrument study, but there were differences. The authors' device measured the positioning on the 3-axis accelerometer, which guaranteed a good agreement and a high reliability by the authors' previous report, phase I, which was less than one degree in error. In addition, the present study device was connected to an android smartphone via the Bluetooth® low-energy system, which made the device cable-less. The sensor was small in dimension and light in weight. Apart from the sensor function, the design added protection for an operative eye from eye-rubbing.

The present study data demonstrated that subjects mimicking the post-operative patients had physiologic limitation by fatigue as the percentage of time in good positioning declined in the third day. Due to the small number of subjects, the authors cannot conclude the correlation about the demographic data with their compliance. However, as the present study subject's mean age was 51.8 years, they should be a good representative of the potential patients. Thus, the high satisfaction and safety score shows that this device is friendly and safe to use. Nevertheless, from the interview, most subjects stated that the real-time audio-vibrating alarm can remind them as a positive trigger to maintain the positioning.

The previous report on the validity of the innovative eye shield[7] showed that the authors' technology had a good internal and external reliability. Hence, the main benefit of the present study supported the safety and the comfort of this sensor in design as an eye-shield to track patient's positioning. Apart from good monitoring function, this design had the potential benefit in the protection of an operated eye after the surgery. The present study showed the feasibility of this innovative device. Thus, using the present study device in post operative intraocular gas/oil patients will be the future step in the effort to improve the patient's positioning compliance.

The main limitation of the present study is that healthy participants might not have a similar willingness to maintain their head position as the pathologic patients. Clinical efficacy using a large sample of pathologic patients is required to reveal the true benefits of this device. There was also a potential selection bias to select volunteering participants in the present study. Therefore, generalization to the patient is limited.

## Conclusion

The innovative eye shield is safe and improves patient compliance in maintaining head positioning after gas-filled intraocular surgery. This instrument might be a benefit to use in routine post-operative care.

## What is already known on this topic?

Head positioning for early post-operative intraocular surgery has been suggested for retinal detachment and macula hole surgery in gas-filled eyes and associate with the success of the surgery. These patients are required to wear eye shields in the early postoperative period.

## What does this study add?

This innovative eye shield with Bluetooth tracking can be worn after surgery to protect and track head position. The innovative eye shield can be used widely in practice after gas-filled surgery and help to increase patient compliance. Research can be done with tracking data to evaluate the impact of head positioning and surgical outcome.

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## Conflict of interests

The authors declare no conflict of interest.

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